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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,842	06/15/2001	Ginette Serrero	A7542.0000/P001-D	7029

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DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L STREET NW
WASHINGTON, DC 20037-1526

EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,842

Applicant(s)

SERRERO, GINETTE

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 13-19, 39-44 and 66-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 20-39 and 45-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's traversal of the election of Group I, claims 1-65, species A (immunological assays) is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and may be examined without a serious burden because art relating to Group I should reveal art relating to the other Groups. This is not found persuasive for reasons indicated in the previous office action, as the Groups have different class/subclass, thus rendering them independent and distinct and a serious burden to search.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-12, 20-39, and 45-65 are being examined as belonging to the elected Group I, as it reads on Species A, while claims 13-19, 41-44, and 66-85 are withdrawn from examination as being drawn to a non-elected invention. 40?

Information Disclosure Statement

1. The information disclosure statements filed 24 October 2001, 15 November 2001, and 2 May 2002 have been considered. A signed copy is attached hereto.

Specification

2. The disclosure is objected to because of the following informalities: The specification discloses preferred embodiments of GP88 mRNA expression in humans as exemplified in example 8 (p. 26). However, the specification does not contain example 8 or examples 2-7. Furthermore, figures 8 and 9 disclose sequences of human GP88 however; the brief description of drawings does not give SEQ ID NOS for the corresponding sequences. Appropriate correction is needed. } drop

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 20-39, and 45-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shoyab, (1991, '510).

Shoyab teach growth modulating proteins called epithelin, the production of antibodies directed against epithelin (p. 18), the expression of epithelin of in various tissue of mice and humans, such as kidney, breast, testis, and ovary (p. 23), "the presence and levels of epithelin in body fluids and tissues may directly or inversely relate to the presence and pervasiveness of certain cancers and other growth related diseases," and assays which can detect and/or quantify epithelins may be used in diagnosis and prognosis of growth related disease (p. 30). Shoyab, et al. further teach an in vivo role for epithelin in terminal differentiation of cell (p. 28). The only difference between the reference and the instant invention is that the reference does not specifically show the direct correlation.

The specification discloses GP88, a growth factor discovered in highly tumorigenic "PC cells" (p. 2), which is interchangeable with PCDGF, as an epithelin/granulin precursor in cell extracts and extracellular fluid (p. 10), which has amino acid similarity with mouse granulin/epithelin precursor (p. 2). Since Shoyab teach the levels of epithelin in body fluids and tissues may be may directly or inversely relate to the presence of cancer(s) and growth related disease, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method as claimed to diagnose tumorigenicity. One would be motivated to determine the ratio of the number of GP88 positive cells to the total number since Shoyab teach a correlation of epithelin and pervasiveness and tumorigenicity of cancer. One would be motivated to use the methods of claims 5-12, 20-21, and 32-39 to detect GP88, since it is well known in the art to use immunoassays to measure protein levels and because Shoyab teach that prognosis may be determined by measuring epithelin levels using assays that may quantify it (p. 30) and teach how to make antibodies using epithelin peptides. In addition, it would be obvious to use the method to determine antineoplastic effects of antiestrogen therapy in an estrogen receptor positive patient since epithelin is expressed in breast cancer (p. 11). Finally, one of ordinary skill in the art would be motivated to use the method as claimed using various tissue such as those in claims 4 and 31 since, Shoyab teach its expression in many tissues (p. 11).

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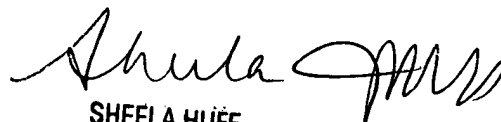
Accordingly, one of ordinary skill in the art would have been motivated to use this method to diagnose tumorigenicity because of the reasonable expectation of success based on well known and accepted methods as indicated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
July 29, 2002


SHEELA HUFF
PRIMARY EXAMINER